REMARKS

Claims 1-18 are all the claims currently pending in this Application. Claims 10-18 are withdrawn. Therefore, claims 1-9 are all the claims currently under consideration.

Listing of the Claims

In the final Office Action, the Examiner notes that in the Response to Restriction Requirement of November 17, 2005, claims 10-18 included incorrect status identifiers. With this Response, Applicants include the above Listing of the Claims, including the proper status identifiers for all claims.

Claim Rejection

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Joseph (U.S. Patent 4,604,087) in view of Molteno (GB 2,101,891). Applicant respectfully traverses this rejection.

The Examiner maintains that the subject matter of claims 1-9 is rendered obvious by Joseph in view of Molteno. Specifically, the Examiner reiterates that the positioning of tube 2 in the anterior chamber through an opening in a cyclodialysis tract necessarily teaches that the tube is adapted to locate Joseph's device on the inner surface of the sclera, in a suprachoroidal space formed by cyclodialysis, as the choroid is on the inner surface of the sclera. In support of this position, the Examiner relies upon the disclosure in Joseph which states as follows: "This figure [Figure 2] also shows the free end of the tube 2 [of the device] entering the anterior chamber 15 through an opening in the cyclodialysis tract 16, the opening being formed surgically."

With respect, the Applicant submits that the Examiner appears to erroneously equate the reference by Joseph to the "opening in a cyclodialysis tract" with the cyclodialysis tract itself, thus forming the view that the device of Joseph is positioned in a suprachoroidal space. With particular reference to Figure 2, the Applicant draws the Examiner's attention to the path traveled by tube 2, commencing with its free end positioned within the anterior chamber 15, lying about one third of the distance between the iris 14 and the cornea 13 (please also refer to text at column 4, lines 6-8). Moving towards the angle between the iris and the cornea, the tube is seen to travel between the ciliary body and the sclera (scleral spur) i.e. along the cyclodialysis tract, for a distance not more than the length of the ciliary body, at which point the tube is directed to the outer surface of the eye, through an opening in the cyclodialysis tract, the opening seen in Figure 2 as an exit point from the interior aspects of the eye to the exterior of the eye.

Thus, the tubing 2 at first travels along a short distance of suprachoroidal space, abutting the ciliary body at its posterior surface and the sclera at its anterior surface. Once outside the eye, the surface of the tubing initially abutting the ciliary body now immediately abuts the outer surface of the sclera. At a short distance, the tubing is then seen to be attached to the drainage body 3, which itself now abuts the outer sclera. The drainage body 3 is wrapped around the exterior of the eye such that in sagittal or transverse cross section (Figure 2), the drainage body is also observed on the opposite side of the eye (placement of reference number 3), also abutting the exterior scleral surface.

Accordingly, Figure 2 (and Figures 4 and 5) clearly shows that a portion of tubing passes within the cyclodialysis tract along the ciliary body, but that the greater portion of Joseph's

device actually sits outside the eye, rather than within a suprachoroidal space, as suggested by the Examiner. Drainage therefore takes place on the scleral surface, rather than within a suprachoroidal space.

The Applicant submits that there are two reasons for using the cyclodialysis tract as an entry point for the tube 2 into the anterior chamber. The first is that this entry pathway conforms with a tube curvature that keeps the end of the tube away from the corneal endothelium, which if damaged will swell and become opaque. This is in fact discussed by Joseph at column 4, lines 9-21. The second reason is that this would distinguish the Joseph shunt from that of Molten for which the entry point for the tube is usually through the sclera near the junction of the sclera with the limbus. For the latter to work, the tube is cut so that not too much protrudes into the anterior chamber. The tube in the Molten shunt ends up having to "bend" into the anterior chamber and this is facilitated by the usual practice of putting a patch graft of sclera over the tube (ostensibly to stop tube erosion through the overlying conjunctiva) as the extra force applied when the scleral patch is sewn over the tube helps to kink it into place.

The Applicant further respectfully submits that numerous disclosures made by Joseph would indicate to a person skilled in the art that Joseph's device could not in fact be positioned within a suprachoroidal space. These disclosures are discussed below.

At column 1, line 63 to column 2, line 2, Joseph states that prior art drainage devices relying on the use of a circular plate(s) as a drainage body do not provide sufficient surface area for sufficient drainage. In consequence, Joseph instead teaches the use of a tyre-like device (drainage body) that clearly fits on the outside of the sclera (Figure 2, drainage body 3).

Therefore, this tyre-like device is distinguished from plates, the latter conceded by Joseph as providing insufficient surface area for drainage.

The drainage body of Joseph is described as a "*band having a width of at least 5mm and a length which is sufficient for the band to pass around, and sutured to, the sclera of the eye in an equatorial position...*" (Column 2, line 19). At column 2, line 59, Joseph also provides that for most eyes, "*the band preferably has a width lying in the range of from 9 to 12 mm*", and at column 5, line 21 and line 23, the width is given as being up to 15 mm or 18 mm, respectively. Notably, Joseph also teaches at column 3, line 59, that the eye (reference number 10 of Figures 2, 4 and 5) is an "*averaged-sized diseased eye, that is to say one having a diameter of about 25 mm.*" Given that in cyclodialysis, by definition, only the ciliary body is detached from the sclera, and that the ciliary body does not extend posteriorly beyond 4.5 -5.2 mm nasally and 5.6-6.3 mm temporally, it would be abundantly clear to a person skilled in the art that Joseph's device, having an average band width of from 9 to 12 mm, would simply not fit in the space created by detachment of the ciliary body. Accordingly, a person skilled in the art would conclude from reading Joseph that his device could not be locatable in the suprachoroidal space on the inner surface of the sclera.

At column 4, lines 41-46, Joseph expresses concerns of the effect of intra-ocular pressure becoming too low as a result of aqueous humor draining too quickly immediately after entering the eye. Joseph explains that this can lead to "*large choroidal detachments forming, which in turn are associated with a tendency to damage the lens of the eye.*" The Applicant submits that if this scenario where to occur, and if Joseph's shunt was suprachoroidal, the risk of choroidal

detachment would be significantly greater, since Joseph's device would be sitting in the suprachoroidal space, facilitating choroidal detachment. Indeed, Joseph teaches placement of his device on the outer scleral surface. Accordingly, the Applicant submits that a person skilled in the art would appreciate that Joseph's shunt would not be appropriate for suprachoroidal placement. Joseph's silence with respect to suprachoroidal placement is particularly relevant given his concerns about choroidal detachment.

At column 2, line 65 to column 3, line 14, Joseph describes attaching extra drainage bodies to his shunt, should the initial shunt procedure not provide sufficient drainage. Specifically, Joseph discusses extension of the tube from the first drainage body to an additional drainage body, stating that "*the additional drainage body can be implanted (preferably under the scalp) some time after the initial operation...this can be accomplished by simple extra-ocular surgery.*" The Applicant submits that in light of this passage, a person skilled in the art would well appreciate that if Joseph's device were in the suprachoroidal space, it would not be possible to connect it to an extra drainage body by an "*extraocular procedure*", as it would be necessary to open the eye, i.e. an intraocular procedure would be required to reach an implant supposedly in the suprachoroidal space. Accordingly, a person skilled in the art would understand without difficulty that Joseph's device could not be positioned suprachoroidally, as this would exclude the possibility of attachment to the device of additional drainage bodies if required. It would be clear to a person skilled in the art that Joseph did not intend to place his device in the suprachoroidal space, and that Joseph's design for a drainage device is reflective of this.

At column 3, lines 62 – 65, Joseph teaches suturing of the shunt to the sclera. Notably, there is no description of how this would be done. The Applicant submits that were Joseph's device to be placed suprachoroidally (hypothetically speaking, as Joseph's device would not fit), suturing the device to the inner surface of the sclera would not be possible without potentially damaging the inner eye. This is because suturing in this case would involve penetration of the needle from the outer surface of the sclera, through the entire thickness of the sclera, and then blindly into an implanted suprachoroidal device. Furthermore, the suprachoroidal space would need to be stabilized as it would move as the needle were being forced into it. Thus, the Applicant submits that a person skilled in the art would not choose to place Joseph's device suprachoroidally and would understand the unsuitability of this device for suprachoroidal positioning, given that Joseph teaches suturing to secure positioning of the device.

In view of the issues presented above, the Applicant submits that the person skilled in the art would not consider Joseph's drainage device to be locatable in the suprachoroidal space. This is particularly the case when these issues are considered together, i.e. in the totality of the teaching by Joseph,

Accordingly, the Applicant reiterates that there is no contemplation by Joseph that the device may be placed anywhere other than on the outer surface of the sclera, let alone to be located on the inner surface of the sclera in a suprachoroidal space formed by cyclodialysis. Further, to construct an aqueous humor drainage device for such a location would not have been contemplated or envisaged by a person skilled in the art prior to the present invention. Accordingly, to argue that the structure of Joseph is capable of being located on the inner surface

of the sclera is essentially immaterial as it would not have been obvious to one of skill in the art to place the Joseph device in such a location.

The Applicant further provides the following comments in support of the assertions made above. Cyclodialysis has indeed previously been considered as a technique for the drainage of aqueous humor. However it had been abandoned well before the priority date of the present application due to complications, chiefly uncontrolled low pressure (hypotony) due to failure of the cyclodialysis to heal spontaneously. Therefore, Glaucoma shunts such as those of Joseph were developed because techniques such as cyclodialysis had failed. When the Joseph shunt was conceived, suprachoroidal surgery had been abandoned and accordingly the last thing that would have been considered by one of skill in the art at the priority date of the present application would be to place a device such as that of Joseph in the suprachoroidal space. Doing so, with a shunt of the size and composition of the Joseph shunt would have resulted in significant trauma to the eye.

There have also been previous attempts at suprachoroidal shunts (see the attached documents; Rosenberg and Krupin, "Implants in Glaucoma Surgery", in *The Glaucomas* (1996), Chapter 88, pages 1783-1807; and Lee et al (1992)) however these had a high complication rate. The GlauRx trabeculo-suprachoroidal implant described in Rosenberg and Krupin (see Figure 881 of the attached document) was a cruciform-shaped device with surface channels along its length draining aqueous from the anterior chamber directly into the suprachoroidal space. However, in a trial of this implant in 13 eyes with neovascular or end-stage glaucoma, four eyes developed hypotony, hyphema was a common complication and five eyes required surgical

revision of the device or a second implant (see paragraph bridging columns 1 and 2 on page 1784). To our knowledge, no shunt that relies on suprachoroidal drainage is in currently in regular clinical use.

In contrast, a shunt of the present invention overcomes the deficiencies in previous shunt designs. The "injectability" of a shunt according to the present invention minimizes trauma to the eye during insertion, such trauma being responsible for the majority of complications of previous designs. Specifically, as claimed in the present invention, the shunt is foldable to fit through a small incision across the anterior chamber and into the space under the sclera in the suprachoroidal space. The device incorporates a tube opening into and remaining in the anterior chamber. A shunt of the present invention will therefore result in greatly reduced fibrosis and enable longer term control of eye pressure than was not possible using shunts and procedures of the prior art.

Importantly, the production of scarring that accompanies the insertion of shunts, as discussed by Joseph at column 1, lines 42-52, and that particularly affects shunts that are on the surface of the sclera and under the conjunctiva is directly addressed by the shunt of the present invention, the basis for which is the fact that typically, there is little if any scarring that occurs in the suprachoroidal space, which is why cyclodialyses mostly do not heal spontaneously. Neither Joseph nor Molteno, when considered either separately or in combination, teach or suggest the placement of a shunt on the inner surface of the sclera in a suprachoroidal space formed by cyclodialysis.

In view of the above, the Applicant submits that claims 1-9 are patentable over Joseph and Molteno, and therefore respectfully request reconsideration and withdrawal of the rejection.

Conclusion and Request for Interview

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. Additionally, Applicant respectfully requests a personal interview with the Examiner at her convenience. The Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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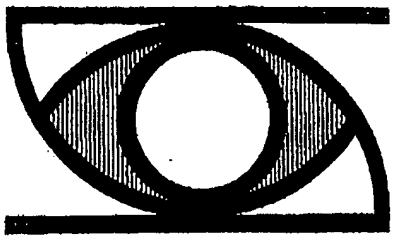
Chapter 88



Implants in Glaucoma Surgery

Lisa F. Rosenberg
Theodore Krupin

The limbal sclerostomy created during filtration surgery serves to bypass conventional outflow pathways and to permit aqueous humor to flow from the anterior chamber to the subconjunctival-Tenon's space. The surgical opening creates a low resistance pathway for aqueous flow and establishes an external filtration bleb. Adjunctive use of subconjunctival injections of 5-fluorouracil (5-FU)[160,167] or intraoperative application of mitomycin C (MMC)[20,146] or 5-FU[149] increases the chance of intraocular pressure reduction in eyes at high risk for filtration failure (see Chapter 81). However, satisfactory filtration may still be difficult to achieve in some cases. Plastic devices offer a different approach to intraocular pressure control. These implants have increased in popularity and are an alternative surgical treatment in eyes with poor surgical prognoses. Reduction of pressure by modern implants is accomplished by shunting of aqueous through an open tube from the anterior chamber to an area of encapsulation around an explant located 8 to 12 mm posterior to the limbus. The critical factor determining intraocular pressure reduction after implant surgery is the resistance of the capsular wall to aqueous humor flow and the total surface area of encapsulation.

HISTORICAL REVIEW

It became apparent early on that the classical glaucoma procedures of sclerectomy,[48] iridencleisis,[54] and corneoscleral trephination[35] were not uniformly successful in achieving long-term control of intraocular pressure. Foreign implantable materials were used to maintain aqueous humor drainage through an ocular wound into the subconjunctival space. These early devices, which were true setons or stents to maintain patency of the fistula, may be categorized as paracentesis drains, cyclodialysis implants, or sclerostomy implants. Many of these devices were usually reported only once with limited experience and follow-up. In general, the long-term results were poor and the complications great, as a result of either excessive ocular inflammation or foreign body reaction leading to filtration failure.

Paracentesis Devices

Rollett and Moreau[131] in 1906 reported placing a horse hair across the anterior chamber through paracentesis incisions to treat two patients with painful absolute glaucoma. Zorab[178] placed a double silk loop covered with a conjunctival flap through a superior keratome incision 2 mm behind the limbus, calling the procedure "aqueoplasty." Mayou,[87] Wood,[176] and Sampimon[134] reported good results with modifications of this procedure in patients with absolute glaucoma. A channelled silicone strip passed from the anterior chamber to the conjunctival sac was described in 1965 for treatment of neovascular glaucoma.[85] Vail[164] placed a silk thread in a track from the vitreous cavity into the subconjunctival space. The suture was removed at 3 months, and the glaucoma did not return for the 2 years before the patient's death. Nevertheless, long-term results with this group of devices were overall very poor because of infection, foreign body reaction, and inflammation.

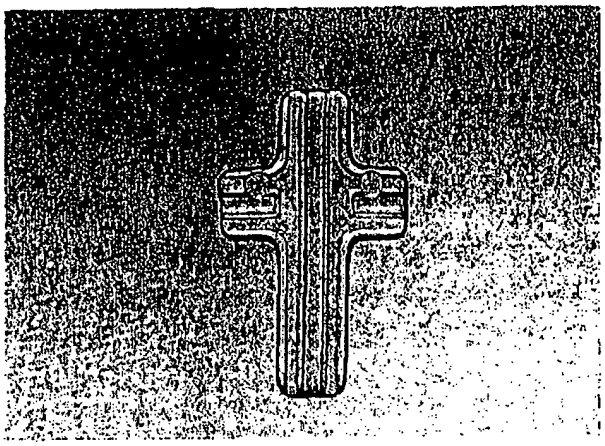


Fig. 88-1 The GlauRx trabeculo-suprachoroidal implant. Aqueous drains through surface channels within the cruciform-shaped implant. (Courtesy Alcon Surgical, Fort Worth, Tex.)

Cyclodialysis Implants

Many materials have been placed within a cyclodialysis with the aim of maintaining patency. In 1934 Row[132] reported placing either a platinum wire or a horse hair within the cleft. Troncosco[162] originally used a magnesium strip[163] and later tantalum foil. Others subsequently used inert plastics (Supramid, gelatin film, Teflon, silicone).* Although these latter materials were well tolerated by the eye, long-term intraocular pressure lowering was poor, probably because of the overall unsuccessful results with cyclodialysis as a glaucoma surgical procedure.

The GlauRx implant (Alcon Surgical, Fort Worth, Tex) is a modern trabeculo-suprachoroidal shunt composed of a thin, cruciform-shaped device made of polymethyl methacrylate (Fig. 88-1). Surface channels along its length drain aqueous from the anterior chamber directly into the suprachoroidal space where it is absorbed.[73] Thus there is no resultant filtering bleb with this type of implant. Under a scleral flap, the long anterior end of the implant is inserted through an incision within the surgical limbus into the anterior chamber, and the posterior end of the implant is inserted through a parallel scleral incision overlying the suprachoroidal space. Thirteen eyes with neovascular or end-stage glaucoma were implanted with the GlauRx shunt.[72] After a mean follow-up of 12 months (range, 7 to 24 months), 11 eyes had intraocular pressure less than 22 mmHg with or without antiglaucoma medication. Four eyes developed hypotony, with pressure less than 9 mmHg. Hyphema was a common complication. Five eyes (38%) required surgical revision of the device or a second implant.

*References 3, 37, 68, 85, 121, 122, 132, 136, 152, 162.

Sclerostomy Setons

A silk thread was the first device to be placed translimbally from the anterior chamber to the subconjunctival space.[178] This was followed by the use of a variety of materials placed translimbally in attempts to prevent closure of the sclerostomy and to act as a "wick" promoting aqueous flow through the anterior chamber opening. These materials have included various plastic plates and rods, gold, tantalum, glass, platinum, cartilage, and lacrimal canalicular tissue.* Most of these devices were associated with postoperative inflammation and fibrosis around the implant, which prevented aqueous humor egress.

Anterior Chamber Shunts to a Distant Site

Tube shunts have been used to direct aqueous from the anterior chamber to a distant site. Mascati[96] connected a plastic anterior chamber tube to the lacrimal sac, and Rajah-Sivayoham[127] connected a silicone anterior chamber tube to a superficial temporal vein. An anterior chamber–venous shunt using a silicone tube inserted into the intrascleral portion of the vortex vein was described by Lee and Wong[74] in 1974. Recently, an open plastic tube shunt from the anterior chamber to the angular vein has been reported.[169] Initial results with these shunts were good; however, there have been no long-term follow-up studies, and to our knowledge they are not frequently used. Obvious difficulties with these devices include erosion of the extraocular portion of the tube and refluxion of contents (tears and blood) into the anterior chamber.

The short Krupin-Denver valve implant (see later discussion) has been used as an anterior chamber shunt to the conjunctival-tear surface.[9] In addition, a modified valve implant containing a filter has been studied in monkey eyes, shunting aqueous humor to the tear layer.[18] This concept provides resistance to aqueous humor flow by the slit-valve, thereby bypassing external (bleb) resistance. However, the potential for reverse flow (tears into the anterior chamber) and endophthalmitis is great, thereby limiting the clinical use of this concept.

Translimbal Tube Shunts

A plastic tube inserted at the limbus into the anterior chamber has the advantage of maintaining a patent conduit for aqueous flow to the subconjunctival space. The open end of the anterior chamber tube, and not the entry incision, is the effective "scleros-

*References 12, 13, 33, 37, 46, 70, 75, 85, 106, 126, 129, 155, 156.

65. Krupin T et al: A long Krupin-Denver valve implant attached to a 180-degree scleral explant for glaucoma surgery, *Ophthalmology* 95:1174, 1988.
66. Krupin T et al: Long-term results of valve implants in filtering surgery for eyes with neovascular glaucoma, *Am J Ophthalmol* 95:775, 1983.
67. Krupin T et al: Valve implants in filtering surgery: a preliminary report, *Am J Ophthalmol* 81:232, 1976.
68. La Rocca V: Gonioplasty in glaucoma: a preliminary report, *Br J Ophthalmol* 46:404, 1962.
69. Latina MA: Single stage Molteno implant with combination internal occlusion and external ligature, *Ophthalmic Surg* 21:444, 1990.
70. Laval J: The use of absorbable gelatin film (gelfilm) in glaucoma filtration surgery, *AMA Arch Ophthalmol* 54:677, 1955.
71. Lavin MJ et al: Clinical risk factors for failure in glaucoma tube surgery: a comparison of three tube designs, *Am J Ophthalmol* 110:480, 1992.
72. KY, Wong SW, Lashkari K: Trabeculo-suprachoroidal shunt for treating recalcitrant and secondary glaucoma. Presented at the American Academy of Ophthalmology meeting, Anaheim, Calif, 1991.
73. Lee KY et al: Magnetic resonance imaging of the aqueous flow in eyes implanted with the trabeculo-suprachoridal glaucoma seton, *Invest Ophthalmol Vis Sci* 33(suppl):948, 1992.
74. Lee PF, Wong WT: Aqueous-venous shunt for glaucoma: report on 15 cases, *Ann Ophthalmol* 6:1083, 1974.
75. Lehman RN, McCaslin MF: Gelatin film used as a seton in glaucoma, *Am J Ophthalmol* 47:690, 1959.
76. Lieberman MF, Egbert PR: Internal suture occlusion of the Molteno glaucoma implant for the prevention of postoperative hypotony, *Ophthalmic Surg* 20:53, 1989.
77. Liebmann JM, Ritch R: Intraocular suture ligature to reduce hypotony following Molteno seton implantation, *Ophthalmic Surg* 23:51, 1992.
78. Lloyd M et al: Echographic evaluation of glaucoma shunts, *Ophthalmology* 100:919, 1993.
79. Lloyd M et al: Clinical experience with the single-plate Molteno implant in complicated glaucomas, *Ophthalmology* 99:679, 1992.
80. Lloyd M et al: Combined Molteno implantation and pars plana vitrectomy for neovascular glaucoma, *Ophthalmology* 98:1401, 1991.
81. Lloyd ME et al: Intermediate-term results of a randomized clinical trial of the 350-mm^2 vs the 500-mm^2 Baerveldt implant, *Ophthalmology* 101:1456, 1994.
82. Lloyd ME et al: Initial clinical experience with the Baerveldt implant in complicated glaucomas, *Ophthalmology* 101:640, 1994.
83. Loeffler KU, Jay JL: Tissue response to aqueous drainage in a functioning Molteno implant, *Br J Ophthalmol* 72:29, 1988.
84. Lotufo DG: Postoperative complications and visual loss following Molteno implantation, *Ophthalmic Surg* 22:650, 1991.
85. MacDonald RK, Pierce MBE: Silicone setons, *Am J Ophthalmol* 59:635, 1965.
86. Mascati NT: A new surgical approach for the control of a class of glaucomas, *Int Surg* 47:10, 1967.
87. Mayou MS: A note on Zorab's operation of aqueoplasty, *Ophthalmoscope* 10:254, 1912.
88. McDermott ML et al: Corneal endothelial cell counts after Molteno implantation, *Am J Ophthalmol* 115:93, 1993.
89. McDonnell PJ et al: Molteno implant for control of glaucoma in eyes after penetrating keratoplasty, *Ophthalmology* 95:364, 1988.
90. Melamed S et al: Postoperative complications after Molteno implant surgery, *Am J Ophthalmol* 111:319, 1991.
91. Mermoud A et al: Molteno tube implantation for neovascular glaucoma: long-term results and factors influencing outcome, *Ophthalmology* 100:897, 1993.
92. Minckler DS, Krupin T: American Glaucoma Society, Mackinaw Island, Mich, 1990.
93. Minckler DS et al: Clinical experience with the single-plate Molteno implant in complicated glaucomas, *Ophthalmology* 95:1181, 1988.
94. Minckler DS et al: The Molteno implant in complicated glaucomas, *Ophthalmol Clin North Am* 1:211, 1988.
95. Minckler DS et al: Experimental studies of aqueous filtration using the Molteno implant, *Trans Am Ophthalmol Soc* 84:368, 1987.
96. Molteno ACB: The dual-chamber single-plate implant, *Aust NZ J Ophthalmol* 18:431, 1990.
97. Molteno ACB: Use of Molteno implants to treat secondary glaucoma. In Cairns JE, ed: *Glaucoma*, London, 1986, Grune & Stratton.
98. Molteno ACB: The optimal design of drainage implants for glaucoma, *Trans Ophthalmol Soc NZ* 33:39, 1981.
99. Molteno ACB: Mechanisms of intraocular inflammation, *Trans Ophthalmol Soc NZ* 32:69, 1980.
100. Molteno ACB: New implant for glaucoma clinical trial, *Br J Ophthalmol* 53:606, 1969.
101. Molteno ACB, Ancker E, Van Biljon G: Surgical technique for advanced juvenile glaucoma, *Arch Ophthalmol* 102:51, 1984.
102. Molteno ACB, Polkinghorne PJ, Bowbyes JA: The Vicryl tie technique for inserting a draining implant in the treatment of secondary glaucoma, *Aust NZ J Ophthalmol* 14:343, 1986.
103. Molteno ACB, Strachan J, Ancker E: Long tube implants in the management of glaucoma, *S Afr Med J* 50:1062, 1976.
104. Molteno ACB, Van Biljon G, Ancker E: Two-stage insertion of glaucoma drainage implants, *Trans Ophthalmol Soc NZ* 31:17, 1979.
105. Molteno ACB, Van Rooyen MMB, Bartholomew RS: Implants for draining neovascular glaucoma, *Br J Ophthalmol* 61:120, 1977.
106. Muldoon WE, Ripple PH, Wilder HC: Platinum implant in glaucoma surgery, *Arch Ophthalmol* 666, 1951.
107. Munoz M, Parrish RK II: Strabismus following implantation of Baerveldt devices, *Arch Ophthalmol* 111:1096, 1993.
108. Munoz M, Parrish R: Hypertropia after implantation of a Molteno drainage device, *Am J Ophthalmol* 113:98, 1992.

109. Munoz M et al: Clinical experience with the Molteno implant in advanced infantile glaucoma, *J Pediatr Ophthalmol Strabismus* 28:68, 1991.
110. Nesher R et al: Molteno implants in children, *J Glaucoma* 1:228, 1992.
111. Netland PA, Walton DS: Glaucoma drainage implants in pediatric patients, *Ophthalmic Surg* 24:723, 1993.
112. Noureddin BN et al: Advanced uncontrolled glaucoma: Nd:YAG cyclophotocoagulation or tube surgery, *Ophthalmology* 99:430, 1992.
113. O'Day DG et al: Graft survival and intraocular pressure control after Molteno valve implantation for postkeratoplasty glaucoma, *Invest Ophthalmol Vis Sci* 33(suppl): 1273, 1992.
114. Omi CA et al: Modified Schocket implant for refractory glaucoma, *Ophthalmology* 98:211, 1991.
115. Oram O et al: Opening an occluded Molteno tube with the picosecond neodymium-yttrium lithium fluoride laser, *Arch Ophthalmol* 112:1023, 1994.
116. Pastor SA et al: Intracameral tissue plasminogen activator: management of a fibrin clot occluding a Molteno tube, *Ophthalmic Surg* 24:853, 1993.
117. Peiffer RL, Popovich KS, Nichols DA: Long-term comparative study of the Schocket and Joseph glaucoma tube shunts in monkeys, *Ophthalmic Surg* 21:55, 1990.
118. Perkins TW: Endophthalmitis after placement of a Molteno implant, *Ophthalmic Surg* 21:733, 1990.
119. Perkins TW et al: Adjunctive mitomycin C in Molteno implant surgery, *Ophthalmology* 102:91, 1995.
120. Philipp W, Klima G, Miller K: Clinicopathological findings 11 months after implantation of a functioning aqueous drainage silicone implant, *Graefes Arch Clin Exp Ophthalmol* 228:481, 1990.
121. Pinnas G, Boniuk M: Cyclodialysis with teflon tube implants, *Am J Ophthalmol* 68:879, 1969.
122. Portney GL: Silicone elastomer implantation cyclodialysis, *Arch Ophthalmol* 89:10, 1973.
123. Prata JA, Minckler DS, Green RL: Pseudo-Brown's syndrome as a complication of glaucoma drainage implant surgery, *Ophthalmic Surg* 24:608, 1993.
124. Prata JA et al: In vitro and in vivo flow: characteristics of glaucoma drainage implants, *Ophthalmology* 102:894, 1995.
125. Price FW, Whitson WE: Polypropylene ligatures as a means of controlling intraocular pressure with Molteno implants, *Ophthalmic Surg* 20:781, 1989.
126. Qadeer SA: Acrylic gonio-subconjunctival plates in glaucoma surgery, *Br J Ophthalmol* 38:353, 1954.
127. Rajah-Sivayoham ISS: Camero-venous shunt for secondary glaucoma following orbital venous obstruction, *Br J Ophthalmol* 52:843, 1968.
128. Richards DW: Intracameral tissue plasminogen activator to treat blocked glaucoma implants, *Ophthalmic Surg* 24:854, 1993.
129. Richards RD, Van Bijsterveld OP: Artificial drainage tubes for glaucoma, *Am J Ophthalmol* 60:405, 1965.
130. Ritch R, Krupin T: Valve implantation forceps for use in glaucoma surgery, *Ann Ophthalmol* 13:1333, 1981.
131. Rollett M, Moreau M: Traitement de le hypopyon par le drainage capillaire de la chambre anterieure [illegible] *Ophthalmol* 25:481, 1906.
132. Row H: Operation to control glaucoma: preliminary report, *Arch Ophthalmol* 12:325, 1934.
133. Rubin B et al: Histopathologic study of the Molteno glaucoma implant in three patients, *Am J [illegible]* 110:371, 1990.
134. Sampimon RLH: A new approach to filtering [illegible] surgery, *Ophthalmologica* 151:637, 1966.
135. Sarkies WJC, Hitchings RA: Silicone tube and [illegible] in advanced glaucoma, *Trans Ophthalmol Soc UK* 104:133, 1985.
136. Sbordone S, Pellegrino A, Galantuomo A: La ciclodialisi secondo Strampeli: considerazioni cliniche e valutazione dei risultati, *Ann Oftalmol e Clin Oculist* 118:415, 1992.
137. Schocket SS: Investigations of the reasons for success and failure in the anterior shunt-to-the-encir[illegible] and procedure in the treatment of refractory glaucoma, *Trans Am Ophthalmol Soc* 84:743, 1986.
138. Schocket SS, Lakhanpal V, Richards RD: Anterior chamber tube shunt to an encircling band in the treatment of neovascular glaucoma, *Ophthalmology* 89:1188, 1982.
139. Schocket SS et al: Anterior chamber tube shunt to an encircling band in the treatment of neovascular glaucoma and other refractory glaucomas: a long-term study, *Ophthalmology* 92:553, 1985.
140. Scott DR, Quigley HA: Medical management of a high bleb phase after trabeculectomies, *Ophthalmology* 95:1169, 1988.
141. Sherwood MB, Joseph NH, Hitchings RA: Surgery for refractory glaucoma: results and complications with a modified Schocket technique, *Arch Ophthalmol* 105:562, 1987.
142. Sherwood MB, Smith MF: Prevention of early hypotony associated with Molteno implants by [illegible] occluding stent technique, *Ophthalmology* 100:8[illegible], 1993.
143. Sherwood MB et al: Drainage tube implants in the treatment of glaucoma following penetrating keratoplasty, *Ophthalmic Surg* 24:185, 1993.
144. Sidoti PA et al: Aqueous tube shunt to a preexisting episcleral encircling element in the treatment of complicated glaucomas, *Ophthalmology* 101:1036, 1994.
145. Sidoti PA et al: Epithelial ingrowth and glaucoma drainage implants, *Ophthalmology* 101:872, 19[illegible]
146. Skuta GL et al: Intraoperative mitomycin vs. postoperative 5-fluorouracil in high-risk glaucoma filtering surgery, *Ophthalmology* 99:438, 1992.
147. Smith M, Sherwood MB, McGorray SP: Comparison of the double-plate Molteno drainage implant with the Schocket procedure, *Arch Ophthalmol* 110:1246, 1992.
148. Smith SL et al: Early clinical experience with the Baerveldt 350-mm² glaucoma implant and associated extraocular muscle imbalance, *Ophthalmology* 100:914, 1993.
149. Smith MF et al: Results of intraoperative 5-fluorouracil supplementation on trabeculectomy for open angle glaucoma, *Am J Ophthalmol* 114:737, 1992.
150. Smyth RJ et al: Pediatric glaucoma valve implantation, *Invest Ophthalmol Vis Sci* 35(suppl):1423, 1994.

151. Spiegel D, Shrader RR, Wilson RP: Anterior chamber tube shunt to an encircling band (Schocket procedure) in the treatment of refractory glaucoma, *Ophthalmic Surg* 23:804, 1992.
152. Stefansson J: An operation for glaucoma, *Am J Ophthalmol* 8:681, 1925.
153. Stewart DH et al: Outcome of Molteno implantation for glaucoma associated with penetrating keratoplasty, *Invest Ophthalmol Vis Sci* 33(suppl):1273, 1992.
154. Stewart W, Feldman RM, Gross RL: Collagen plug occlusion of Molteno tube shunts, *Ophthalmic Surg* 24:47, 1993.
155. Stone W: Alloplasty in surgery of the eye. I., *N Engl J Med* 258:486, 1958.
156. Stone W: Alloplasty in surgery of the eye. II., *N Engl J Med* 258:533, 1958.
157. Susanna R: Modifications of the Molteno implant and implant procedure, *Ophthalmic Surg* 22:611, 1991.
158. Susanna R, Nicolela MT, Takahashi WY: Mitomycin C adjunctive therapy with glaucoma implant surgery, *Ophthalmic Surg* 25:458, 1994.
159. Tam MYM et al: Preliminary results of glaucoma valve implant clinical trial, *Invest Ophthalmol Vis Sci* 35 (suppl):1914, 1994.
160. The Fluorouracil Filtering Surgery Study Group: Fluorouracil filtering surgery study 1-year follow-up, *Am J Ophthalmol* 108:625, 1989.
161. Traverso CE, Tomey KF, al-Kaff A: The long-tube single-plate Molteno implant for the treatment of recalcitrant glaucoma, *Int Ophthalmol* 13:159, 1989.
162. Troncosco MU: Use of tantalum implants for inducing a permanent hypotony in rabbits' eyes, *Am J Ophthalmol* 32:499, 1949.
163. Troncosco MU: Cyclodialysis with insertion of a metal implant in the treatment of glaucoma: a preliminary report, *Arch Ophthalmol* 23:270, 1940.
164. Vail DT: Retained silk thread or 'seton' drainage from vitreous chamber to Tenon's lymph channel for the relief of glaucoma, *Ophthal Rec Chicago* 24:184, 1915.
165. Waterhouse WJ et al: Rhegmatogenous retinal detachment after Molteno glaucoma implant surgery, *Ophthalmology* 101:665, 1994.
166. Watzke R: Scleral patch graft for exposed episcleral implants, *Arch Ophthalmol* 102:114, 1984.
167. Weinreb RN: Adjusting the dose of 5-fluorouracil after filtration surgery to minimize side effects, *Ophthalmology* 94:564, 1987.
168. Wellemeyer ML, Price FW: Molteno implants in patients with previous cyclocryotherapy, *Ophthalmic Surg* 24:395, 1993.
169. Welsh NH et al: Veno-cameral shunt in end-stage glaucoma, International Glaucoma Symposium, Jerusalem, 1991.
170. White TC: Clinical results of glaucoma surgery using the White glaucoma pump shunt, *Ann Ophthalmol* 24:365, 1992.
171. Wilcox MJ, Minckler DS, Ogden TE: Pathophysiology of artificial aqueous drainage in primate eyes with Molteno implants, *J Glaucoma* 3:140, 1994.
172. Williamson W et al: Le tube de Schocket: étude retrospective à propos de 36 cas, *J Français D'Ophtalmologie* 16:506, 1993.
173. Wilson RP: The Schocket shunt. In *Ophthalmology Clinics of North America*, Philadelphia, 1988, WB Saunders.
174. Wilson RP et al: Aqueous shunts: Molteno versus Schocket, *Ophthalmology* 99:672, 1992.
175. Wilson-Holt N et al: Hypertropia following inferiorly sited double-plated Molteno tubes, *Ophthalmology* 9(suppl):143, 1990.
176. Wood CA: The sclerocorneal seton in the treatment of glaucoma, *Ophthal Rec Chicago* 24:235, 1915.
177. Wright MM, Singh K, Grajewski AL: Polypropylene suture stent for insertion of glaucoma tube shunt implants, *Ophthalmic Surg* 25:743, 1994.
178. Zorab A: The reduction of tension in chronic glaucoma, *Ophthalmoscope* 10:258, 1912.

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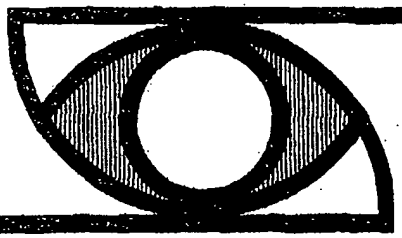

THE GLAUCOMAS

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Paper Presentation

TUESDAY 5/5

1279 — 9:30

SURGICAL MANAGEMENT OF GLAUCOMA IN THE IRIDOCORNEAL ENDOTHELIAL SYNDROME. James C. Tsai, Mary Ann Lloyd, Dale K. Heuer, George Baerveldt, Don S. Minckler, and Paul P. Lee. University of Southern California and Doheny Eye Institute, Los Angeles, California.

Fourteen eyes of 14 patients who underwent surgery for medically uncontrollable glaucoma associated with the iridocorneal endothelial syndrome were retrospectively reviewed. Nine patients had Chandler's syndrome, three had essential iris atrophy, and two had the iris nevus syndrome. Eight patients (57%) had previously failed one or more filtering procedures. The mean IOP prior to surgery at our institution was 35.2 ± 9.2 mm Hg (range 19-55 mm Hg). Surgical success was defined as 6 ≤ final IOP ≤ 21 mm Hg without additional glaucoma surgery or devastating complication.

Four of the five patients who underwent trabeculectomies without postoperative 5-fluorouracil (5-FU) failed at a mean of 11.8 ± 13.0 months (range 5-35 months). The one patient who underwent trabeculectomy with postoperative 5-FU was successful at 37 months. One patient who underwent Hoskins-Drake implantation was a qualified failure at three months (IOP = 28 mm Hg). Seven patients underwent Molteno implantation as their initial procedure [double plate (four patients), single plate (three patients)]. In addition, four of the patients who failed trabeculectomies eventually received either a single or double plate Molteno implant (two patients each). With a mean follow-up of 20.8 ± 13.4 months (range 6-43 months), all six patients with double plate Molteno implants were successful on one medication each. Four out of five patients who underwent single plate Molteno implantation failed at a mean of 7.8 ± 7.0 months (range 3 days-17 months). Three of those patients who failed achieved successful IOP control after undergoing an additional single plate Molteno installation.

N

1280 — 9:45

CATARACT SURGERY IN THE PRESENCE OF A FILTERING BLEB WITH POSTOPERATIVE 5-FLUOROURACIL(5-FU). Murray A. Johnstone, and Carol I. Ziel. Swedish Hospital, Seattle Washington.

Cataract surgery performed in the presence of a filtering bleb causes some blebs to fail requiring repeat filtration surgery. In an attempt to increase the survival of blebs after cataract surgery we treated a group of patients (n=20, mean follow up 9.8 months) with low dose 5-FU (mean total dose 12.0 mg. 5-FU). The 5-FU was introduced into the area of the bleb from the adjacent quadrant under slitlamp control during the first two weeks after cataract surgery. We retrospectively compared the 5-FU group to patients with a functioning bleb undergoing cataract extraction without 5-FU (n=33, mean followup 23 months). There was no significant difference between the two groups in terms of age, race, sex, preoperative (preop) intraocular pressure (IOP), number of preop medications used, and time to cataract extraction. In the non-5-FU group 5 patients (15%) failed, all within six months, (3 required repeat filtration surgery, and 2 required revision of their blebs). In the 5-FU group all patients (100%) maintained an IOP of less than or equal to 20 mm Hg without further surgery. Of those who maintained the function of their blebs, there was no significant difference between the groups in the postoperative IOP at 1, 6, and 12 months. However the 5-FU group used fewer postoperative medications (0.38 meds) than the non-5-FU group (0.93 meds) ($P < 0.05$). Complications unique to the 5-FU group were those of corneal toxicity; stippie (8/20), and epithelial defects (4/20). These results suggest that adjunctive low dose 5-FU injected into the area of the bleb may prolong the function of filtration blebs after cataract extraction.

1281 — 10:00

TRABECULECTOMY WITH RELEASABLE SCLERAL FLAP SUTURES AND ADJUNCTIVE LOW DOSE 5-FLUOROURACIL VERSUS MOLTENO IMPLANT IN ADVANCED APHAKIC AND PSEUDOPHAKIC GLAUCOMA. Ronald P. Swendris, Eamin Chou, Dong H. Shin, Kyle A. Parrow, Ki-Bang Uhm, Mark S. Juzych. Kresge Eye Institute, Wayne State University, Detroit, MI 48201.

Success of filtering surgery for uncontrolled glaucoma after cataract extraction is often limited due to conjunctival scarring. The choice is often to attempt a trabeculectomy in unscarred conjunctiva or a remote filtering explant. We incorporated releasable scleral flap sutures with low-dose adjunctive 5-Fluorouracil (average 3.7, 5 mg injections, range 2 to 6) to improve the success rate in 4 aphakic and 13 pseudophakic patients undergoing trabeculectomy; while a parallel cohort of 5 aphakic and 15 pseudophakic patients underwent single-plate Molteno implant with a releasable internal ligature:

Group	Follow-up	Postop IOP	Postop Meds	Success	Visual result
Filter (N=17)	11.4±5.1 mos (4-22)	17.1±5.2 (6-26)	1.8±1.0 (0-3)	76%≤22 mm* 71%≤20 mm†	94% stable/better 6% worse
Molteno (N=20)	11.8±4.4 mos (3-19) p=NS	16.5±5.9 (5-28) p=NS	2.5±1.2 (0-4) p=.055	65%≤22 mm* 75%≤20 mm† *p=.76 †p=.81	65% stable/better 35% worse p=.03

Preoperative IOP, glaucoma medications, and C/D ratio were similar in both groups. Patients undergoing Molteno implant had poorer initial vision, and had undergone more previous anterior segment and glaucoma surgery. The spectrum of complications was strikingly different, with Molteno cases tending to more severe postoperative difficulties. In appropriately selected patients, both modified trabeculectomy and Molteno implantation can be very successful. Each procedure has its own unique limitations and complications; knowledge of these is critical for successful control of IOP with preservation of vision.

1282 — 10:15

GLAUCOMA VALVE TO AN EXTERNAL DISK EXPLANT FOR FILTRATION SURGERY. T. Krupin[1], JR Ruderman[2], LF Rosenberg[3], ME Feldt[3], R Ritch[4], JM Liebmann[4], CB Camras[5], JB Serle[6], SM Podos[6]. Departments of Ophthalmology, [1]Northwestern University, [2]Geisinger Clinic, [3]New York Eye and Ear Infirmary, [4]University of Nebraska, [5]Mt. Sinai Medical Center, New York.

A large Silastic disk (13 mm X 18 mm) has been fabricated for the episcleral plate of a posterior shunt filtration device (E. Benson Hood Laboratories, Pembroke, MA). The explant has a 1.75 mm high side wall to promote a larger area of encapsulation. The anterior chamber connecting tube contains a pressure-sensitive and unidirectional slit-valve which opens on the surface of the disk explant. The valve has an opening pressure of 12 mm Hg and a closing pressure of 9 mm Hg. The disk is attached to the sclera, in a quadrant between two adjacent rectus muscles, 10 to 12 mm posterior to the limbus.

The disk device has been used in 50 eyes since February 1990. Attachment of the explant was easily performed except in one eye which had a prior encircling explant. Aqueous humor restrictive devices were not placed around or within the anterior chamber tube.

Mean (± SEM) preoperative IOP was 38 ± 2 mm Hg. Early postoperative IOP and anterior chamber depth (ACD: 4 = no iris/corneal contact; 3 = peripheral contact; 2 = 50% contact; 1 = complete iris/corneal contact; 0 = corneal/lenticular contact) were as follows:

	Postoperative Interval			
	1st day	1 week	2 weeks	1 month
IOP (mean ± SEM)	7.6 ± 1.6	9.1 ± 1.6	8.4 ± 1.4	13.5 ± 1.6
ACD (range)	3.4 ± 0.2 (1 - 4)	3.4 ± 0.1 (2 - 4)	3.6 ± 0.1 (2 - 4)	3.8 ± 0.1 (3 - 4)

Mean IOP 6 months after surgery was 15.9 ± 1.5 (range 9 to 32) mm Hg. IOP was ≤ 19 mm Hg in 81% of eyes: 60% without medications.

The authors have no proprietary interest in the development or marketing of the device.

None

1283 — 10:30

OPENING/CLOSING PRESSURES AND FLOW RATES OF KRUPIN-DENVER VALVES IN AIR AND/OR WATER. BM Scravite, CB Toris, CB Camras, and MG Yablonski. Dept. of Ophthal., Univ. of Nebraska Med. Ctr, Omaha.

In spite of the use of unidirectional, pressure-sensitive Krupin-Denver valves to reduce postoperative hypotony for after tube shunt procedures, IOPs lower than the presumed opening pressure (OP) for these valves may occur. The mechanical properties of these valves, including the OP and closing pressure (CP) in water and air, have not been previously reported. Five valves (Denver Biomaterials, Denver, CO) were connected to a 100µl Hamilton syringe via wide-bore tubing. The whole system was filled with degassed, colored water and the outer end of the valved device was either in contact with air or submerged in water. OPs were determined by slowly raising the horizontally-mounted micrometer syringe along a metric ruler and observing the height at which the meniscus in the syringe first moved; and CPs were determined by slowly lowering the syringe until the meniscus stopped moving. Flow rates in water were determined by measuring the meniscus movement along the syringe over a set time period, and thereby the volume of water passing through the valve, at the OP of each valve and at 10mm Hg. Three to 5 determinations of OP/ CP pressure and flow rates were made for each valve. The meniscus drag was 0.3mm Hg in the micrometer syringe. OPs/CPs were significantly ($p<0.01$) higher in air (10.4±1.4/7.3±1.7mm Hg, mean ±SEM) than in water (4.7±0.5/3.1±0.6mm Hg). Flow rates measured at 10mm Hg (87.1±47.5µl/min) were higher than those measured at the OP (18.9±2.8µl/min), both of which were considerably greater than normal aqueous flow. Marked intra- and inter-variability in the OP/CP and flow rates was apparent for the multiple measurements made in each of the 5 valves. Although the OPs/CPs of these valves are purportedly in the 11-14/9-12mm Hg range, our results demonstrate lower values in water. We recommend that the OP/CP be tested with the valve tip in water to simulate the clinical situation. Our findings may account for postoperative IOPs measured at levels below the presumed CPs of the valves, although many other pathophysiological factors may also contribute to the hypotony.

IOVS 33(Suppl) 948, 1492

1284 — 10:45

MAGNETIC RESONANCE IMAGING OF THE AQUEOUS FLOW IN EYES IMPLANTED WITH THE TRABECULO-SUPRACHOROIDAL GLAUCOMA SETON. King Y. Lee[1], Kameran Lashkari[1], Kenneth K. Kwong[2], Hong-Ming Cheng[2]. [1]Dept. of Ophthalmology, University of Missouri, Eye Foundation of Kansas City, Kansas City, MO. [2]Howe Laboratory of Ophthalmology, Harvard Medical School Boston, MA.

The trabeculo-suprachoroidal shunt (TSS) is a newly devised glaucoma seton which is designed to channel the aqueous humor from anterior chamber to the suprachoroidal space, where it is cleared by the choroidal circulation. This mechanism of action has been postulated but not proven. Eyes with hemorrhagic neovascular glaucoma were implanted with TSS and examined with high-resolution gadolinium-DTPA (GdDTPA) enhanced magnetic resonance imaging. TSS was the only means of aqueous outflow in these eyes. Following intravenous injection, GdDTPA enhanced the ciliary body and then concentrated in the anterior chamber. It then rapidly enhanced in the suprachoroidal region at and near the implant site. There was a sharp demarcation between enhanced and non-enhanced choroidal regions suggesting rapid run-off through the vortex veins. No GdDTPA entered the vitreous or diffused across the sclera. In addition, choroidal enhancement was not observed in non-functioning (obstructed) shunts.

These results indicate that the aqueous flowed from the anterior chamber to the suprachoroidal space and that the action of TSS is in fact, suprachoroidal drainage.

948

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